PTO/SB/05 (03-01)

Approved for use through 10/31/2002. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## UTILITY PATENT APPLICATION

Attorney Docket No.	CSI 130				
First Inventor	Donald L. Wise				
Title Vaccines to In-	duce Mucosal Immunity				

TRA	NSMITTAL	Title	Vaccines to Induc	e Mucos	al Im	, ,	
(Only for new nonprovision	nal applications under 37 CFR 1.53(b)	_	ss Mail Label No.	EL 71774	6904	us	
APPLICA	TION ELEMENTS	AD	DDCCC TO.	sistant Co		ioner for Patents	
See MPEP chapter 600 cond	erning utility patent application conte	nts.	W	ashington,	DC 20	0231	
	orm (e.g., PTO/SB/17) duplicate for fee processing)	7. [	CD-ROM or CD-R			e table or	
Applicant claims s See 37 CFR 1.27.	mall entity status.		Computer Program (Appendix)  8. Nucleotide and/or Amino Acid Sequence Submission  (if applicable of programs)				
3. Specification (preferred arrangement)	[Total Pages 37 ]	(if applicable, all necessary)  a. Computer Readable Form (CRF)					
' - Descriptive title	of the invention e to Related Applications	b.	Specification Sequence	e Listing o	n:		
	arding Fed sponsored R & D		i. 🗌 CD-ROM	or CD-R (2	2 copie	es); or	
	quence listing, a table,		ii. 🗹 paper				
- Background of	rogram listing appendix the Invention	C.	✓ Statements verification	ying identit	y of at	oove copies	
- Brief Summary	of the Invention n of the Drawings ( <i>if filed</i> )		ACCOMPANYING	APPLIC	CATIO	ON PARTS	
<ul> <li>Detailed Descri</li> </ul>		9.	Assignment Pape				
- Claim(s)	Pie ele acces		37 CFR 3.73(b) \$	•		Power of	
- Abstract of the	[ <u>-</u>	10	(when there is an	-		☐ Attorney	
4. Drawing(s) (35 U	.S.C. 113) [Total Sheets	] ] [11]	English Translati		ent (IT 8	Copies of IDS	
5. Oath or Declaration	[ Total Pages 1	] ] 12.	Statement (IDS)		L	Citations	
a. Newly executed (original or copy) 13. Preliminary Amendment							
b. Copy from a prior application (37 CFR 1.63 (d)) (for continuation/divisional with Box 18 completed)  Return Receipt Postcard (MPEP 503) (Should be specifically itemized)				·			
i. DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s)  15. (if				Certified Copy of Priority Document(s) (if foreign priority is claimed)			
named in the prior application, see 37 CFR  16 Nonpublication Request under 35 U.				U.S.C. 122			
1.53(d)(2) and 1.33(b). (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.							
6. Application Data	Sheet. See 37 CFR 1.76	17.			•••••		
18. If a CONTINUING APPLI	CATION, check appropriate box, and	supply the re	quisite information below	v and in a i	orelimi	nary amendment,	
or in an Application Data She			•	•		·	
Continuation	Divisional Continuation-in-part (	CIP)	of prior application No.:	/			
Prior application information:	Examiner:		Group Art Uni				
Box 5b, is considered a part of	ONAL APPS only: The entire disclosure f the disclosure of the accompanying co	ntinuation or	divisional application and	is hereby in	ncorpo	rated by reference.	
The incorporation can only be	relied upon when a portion has been ina			application	parts.		
	19. CORRESPO				_		
Customer Number or Bar Co	Instair Quistioner Aus or Alife		or	Correspon	dence a	ddress below	
Name	Patrea L. Pabst PATENT 8 Holland & Knight LLP	TRADEMARK OFFI	DE				
	2000 One Atlantic Center						
Address	1201 West Peachtree Street						
City	Atlanta	State	GA	Zip C	Code	30309-3400	
Country	United States	Telephone	ne 404-817-8473		ax .	404-817-8588	
Name (Print/Type)	Rivka D. Monheit	Re	gistration No. (Attom	ey/Agent)	48,7	731	
Signature	Rivlia D. Mouher &			Date	July	3, 2003	

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

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FEE TRANSMITTAL		Complete if Known			
FEE IRAN	SIVIIIIAL	Application Number	Not yet assigned		
for FY 2003  Effective 01/01/2003. Patent fees are subject to annual revision.  Applicant claims small entity status. See 37 CFR 1.27		Filing Date	July 3, 2003		
		First Named Inventor	Donald L. Wise		
		Examiner Name	Not yet assigned		
		Art Unit	Not yet assigned		
TOTAL AMOUNT OF PAYMENT	(\$) 384.00	Attorney Docket No.	CSI 130		

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)					
Check Credit card Money Other None 3. ADDITIONAL FE					s	
Deposit Account:	Large Entity   Small Entity					
Deposit 50 4000	Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
Account Number 50-1868	1051	130	2051	65	Surcharge - late filing fee or oath	
Deposit Account Holland & Knight LLP	1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
Name The Commissioner is authorized to: (check all that apply)	1053	130	1053	130	Non-English specification	<b></b>
Charge fee(s) indicated below Credit any overpayments	1812	2,520	1812	2,520	For filing a request for ex parte reexamination	<b></b>
Charge any additional fee(s) during the pendency of this application	1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
FEE CALCULATION	1251	110	2251	55	Extension for reply within first month	ļ
1. BASIC FILING FEE	1252	410	2252	205	Extension for reply within second month	<b>├</b>
Large Entity Small Entity	1253	930	2253	465	Extension for reply within third month	
Fee Fee Fee Fee Pee Paid Code (\$) Code (\$)	1254	1,450	2254	725	Extension for reply within fourth month	
1001 750 2001 375 Utility filing for	1255	1,970	2255	985	Extension for reply within fifth month	<b>├</b> ──
1002 330 2002 165 Design filing fee 375.00	1401	320	2401	160	Notice of Appeal	<u> </u>
1003 520 2003 260 Plant filing fee	1402	320	2402	160	Filing a brief in support of an appeal	
1004 750 2004 375 Reissue filing fee	1403	280	2403	140	Request for oral hearing	
1005 160 2005 80 Provisional filing fee	1451	1,510	1451	1,510	Petition to institute a public use proceeding	
SUBTOTAL (1) (\$) 375.00	1452	110	2452	55	Petition to revive - unavoidable	<u> </u>
	1453	1,300	2453	650	Petition to revive - unintentional	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE Fee from		1,300	2501	650	Utility issue fee (or reissue)	
Extra Claims         below         Fee Paid           Total Claims         21         -20         1         x         9.00         =         9.00	1502	470	2502		Design issue fee	
Independent 3 2** 0 v 00 d 00	1503	630	2503		Plant issue fee	
Claims -3 - 0 ^ .00000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000000	1460	130	1460		Petitions to the Commissioner	
	1807	50	1807	-	Processing fee under 37 CFR 1.17(q)	
Fee Fee Fee Fee Description	1806	180	1806		Submission of Information Disclosure Stmt	<u> </u>
Code (\$)	8021	40	802°	1 40	Recording each patent assignment per property (times number of properties)	
1202 18 2202 9 Claims in excess of 20 1201 84 2201 42 Independent claims in excess of 3	1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1203 280 2203 140 Multiple dependent claim, if not paid	1810	750	2810	375	For each additional invention to be	
1204 84 2204 42 ** Reissue independent claims	4004	750			examined (37 CFR 1.129(b))	
over original patent  1205 18 2205 9 ** Reissue claims in excess of 20	1801 1802	750 900	2801 1802	900	Request for Continued Examination (RCE)  Request for expedited examination	
and over original patent	1002	900	1002	900	of a design application	
SUBTOTAL (2) (\$) 9.00	Other	fee (sp	ecify) _			
**or number previously paid, if greater; For Reissues, see above *Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) .00						
SUBMITTED BY (Complete (if applicable)						

Registration No. Rivka D. Monheit Name (Print/Type) 48,731 Telephone (404) 817-8514 (Attorney/Agent) D. Monhest Sianature July 3, 2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231. 077044/00010

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald L. Wise, Debra J. Trantolo, David D. Hile and Stephen A. Doherty

Serial No.: Express Mail Label No.: EL 717746904 US

Filed: July 3, 2003 Date of Deposit: July 3, 2003

For: VACCINES TO INDUCE MUCOSAL IMMUNITY

Mail Stop Patent Application Commissioner of Patents and Trademarks Alexandria, VA 22313-1450

## EXPRESS MAIL TRANSMITTAL LETTER FOR PATENT APPLICATION AND CERTIFICATE OF MAILING

Sir:

Pursuant to 35 U.S.C. § 21(a) as amended by Public Law 97-247 and 37 C.F.R. § 1.10, applicants enclose for filing the attached patent application entitled "Vaccines to Induce Mucosal Immunity", which claims priority to U.S.S.N. 60/393,777 filed July 3, 2002. The application includes 1 page of abstract, 34 pages of specification, 2 pages of claims, 1 sheet of formal drawing, and an unexecuted Declaration for Patent Application. An executed Declaration for Patent Application, Assignment of rights in the application from Donald L. Wise, Debra J. Trantolo, David D. Hile and Stephen A. Doherty to Cambridge Scientific, Inc., Power of Attorney or Authorization of Agent, and a Statement Under 37 C.F.R. § 3.73(b) will be submitted shortly.

This application contains nucleic acid and/or protein sequences as defined in 37 C.F.R. §§ 1.821-1.825. Pursuant to 37 C.F.R. §§ 1.821-1.825, applicants enclose a 3½" diskette

Title: VACCINES TO INDUCE MUCOSAL IMMUNITY

Filed: JULY 3, 2003

Express Mail Transmittal Letter for

Patent Application and Certificate of Mailing

Express Mail Label No.: EL 717746904 US

Date of Deposit: July 3, 2003

containing a computer-readable form of the Sequence Listing for the above-identified

application. A paper copy of the Sequence Listing is incorporated into the application.

I declare that the material on the diskette is identical to the paper copy of the Sequence

Listing present in the above-identified application, and that all statements made on information

and belief are believed to be true and further that these statements were made with the

knowledge that willful false statements may jeopardize the validity of the application or any

patent issuing thereon.

Commissioner is authorized to charge Deposit Order Account No. 50-1868 in the amount

of \$384.00 to cover the filing fee for a small entity. It is believed that this is the proper filing fee

for a small entity as the application contains 3 independent claims, and a total of 21 claims.

This application is entitled to claim small entity status under 37 C.F.R. § 1.27.

This application is being filed on July 3, 2003 by mailing the application to Box Patent

Application, Commissioner of Patents and Trademarks, Alexandria, VA 22313 via the United

States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10.

The Express Mail label number appears in the heading of this paper which is attached to the

application papers pursuant to 37 C.F.R. § 1.10(b).

The Commissioner is hereby authorized to charge any additional fees that may be

required, or credit any overpayment in connection with this application, to Deposit Order

Account No. 50-1868. To facilitate this process, applicants have enclosed a duplicate of this

transmittal.

077044/00010

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Title: VACCINES TO INDUCE MUCOSAL IMMUNITY

Filed: JULY 3, 2003

Express Mail Transmittal Letter for Patent Application and Certificate of Mailing Express Mail Label No.: EL 717746904 US

Date of Deposit: July 3, 2003

All correspondence concerning this application should be mailed to:

Patrea L. Pabst, Esq. HOLLAND & KNIGHT LLP Suite 2000, One Atlantic Center 1201 West Peachtree Street, N.E. Atlanta, Georgia 30309-3400

(404) 817-8473 (Telephone) (404) 817-8588 (Fax)

Respectfully submitted,

Rivka D. Monheit

Reg. No. 48,731

Date: July 3, 2003

HOLLAND & KNIGHT LLP Suite 2000, One Atlantic Center 1201 West Peachtree Street, N.E. Atlanta, Georgia 30309-3400 (404) 817-8514 (Telephone) (404) 817-8588 (Fax) Title: VACCINES TO INDUCE MUCOSAL IMMUNITY

Filed: JULY 3, 2003

**Express Mail Transmittal Letter for** 

Patent Application and Certificate of Mailing Express Mail Label No.: EL 717746904 US

Date of Deposit: July 3, 2003

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10** 

I hereby certify that this Express Mail Transmittal Letter for Patent Application and

Certificate of Mailing and any documents referred to as attached therein are being deposited with

the United States Postal Service on this date, July 3, 2003, in an envelope as "Express Mail Post

Office to Addressee" service under 37 C.F.R. § 1.10, Express Mail Label No. EL 717746904 US,

addressed to Box Patent Application, Commissioner of Patents and Trademarks, Alexandria, VA

22313.

Pam Turnbough

Date: July 3, 2003

ATL1 #583855 v1

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